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Title:	Surgery for obesity and related diseases : official journal of the American Society for Bariatric Su
Title Abbrev:	Surg Obes Relat Dis
Citation:	2008 Jan 31; [Epub ahead of print]
Article:	Studies of Swedish adjustable gastric band and Lap
Author:	Cunneen SA;Phillips E;Fielding G;Banelb S D;Estok R;Fahrbach
NLM Unique ID:	101233161 Verify: PubMed
PubMed UI:	18243061
ISSN:	1550-7289 (Print)
Publisher:	Elsevier,, New York, N.Y. :
Copyright:	Copyright Compliance Guidelines
Authorization:	Lisa Eblen
Need By:	N/A
Maximum Cost:	**$12.00**
Patron Name:	Chastanet, [71]
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SURGERY FOR OBESITY AND RELATED DISEASES

Surgery for Obesity and Related Diseases xx (2008) xxx–xxx

Review

Studies of Swedish adjustable gastric band and Lap-Band: systematic review and meta-analysis

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Received July 16, 2007; revised October 7, 2007; accepted October 19, 2007

Abstract

Background: This is the first systematic review and meta-analysis of the large body of data describing the Swedish adjustable gastric band (SAGB) and Lap-Band (LB).

Methods: A systematic review was performed that included screening of studies published in any language (January 1, 1998 through April 30, 2006) identified through MEDLINE, Current Contents, or the Cochrane Library. Studies with ≥10 SAGB or LB patients reporting ≥30-day efficacy or safety outcomes were eligible for review; the data were extracted from the accepted studies. A weighted means analysis and random-effects meta-analysis of efficacy outcomes of interest were conducted.

Results: A total of 4592 bariatric surgery studies met the initial criteria. Of these studies, 129 (28,980 patients) were accepted (33 SAGB and 104 LB studies); most had a retrospective single-center design. For 4273 patients (36 treatment groups) in 33 SAGB studies and 24,707 patients (111 groups) in 104 LB studies, the mean baseline age (39.1–40.2 yr), body mass index (43.8–45.3 kg/m^2), and gender (women 79.2–82.5%) were similar. A laparoscopic technique was used in ≥88% and a pars flaccida technique in ≥41% of both groups. Early mortality was equivalent for SAGB/LB (≤.1%). The 3-year mean SAGB and LB excess weight loss (56.36% and 50.20%, respectively) and body mass index reduction (−11.99 and −11.81 kg/m^2, respectively) from baseline were statistically significant ($P < .05$), as was the resolution of diabetes (61.45% and 60.29%, respectively) and hypertension (62.95% and 43.58%, respectively). Although scant and inconsistently reported data precluded direct statistical comparisons, the complication rates for the 2 devices appeared comparable. In 8 directly comparative studies, meta-analysis found a significantly greater absolute weight loss ($P < .05$) with the SAGB at 2 years (48.4 versus 41.9 kg, mean difference −4.84, 95% confidence interval −9.47 to −0.22), although no difference was found in the percentage of excess weight loss or change in body mass index.

Conclusion: In a systematic review of the published world SAGB and LB data, at 1, 2, and 3 years, the weight loss, resolution of diabetes and hypertension, and complications appeared comparable. (Surg Obes Relat Dis 2008;xx:xxx–xxx.) © 2008 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Morbid obesity; Laparoscopic adjustable gastric band; LAGB; Swedish adjustable gastric band; Lap-Band; Weight; Systematic review; Meta-analysis

This work was supported by Ethicon Endo-Surgery, a Johnson & Johnson Company, Cincinnati, Ohio

Presented at the 24th Annual Meeting of the American Society for Bariatric Surgery, June 11–16, 2007, San Diego, California

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doi:10.1016/j.soard.2007.10.016

At the outset of the 21st century, bariatric surgery is the best available therapy [1–5] for the global epidemic of morbid obesity (body mass index [BMI] ≥40 or ≥35 kg/m^2 in the presence of high-risk co-morbidities) [6–9]. Implanted in >100,000 procedures [10], laparoscopic adjustable gastric banding (LAGB), a restrictive operation [11], is 1 of several weight-loss operations (i.e., LAGB, vertical banded gastroplasty, gastric bypass, biliopancreatic diversion/duodenal switch) to have demonstrated efficacy characterized by clinically meaningful (≥50%) excess weight loss and co-morbidity reduction in the short (1–3 yr) and intermediate (≥3–8 yr) terms [12–17]. LAGB also carries the benefits of minimal invasiveness [18], is associated with a premier perioperative safety record [12,19–23], is frequently selected by patients [24], and has the lowest mortality (<.05%) of the bariatric procedures [14,21,22].

LAGB patients benefit from swift operative times of 30–60 minutes [25], minimal postoperative pain, a brief hospital stay, and a relatively rapid recovery involving minimal scarring. The hallmark of the LAGB procedure is an adjustability that facilitates individualized, modifiable, external band restriction such that short-term changes in nutritional requirements (e.g., pregnancy, illness) can be accommodated [13,26,27]. The LAGB procedure is also reversible, allowing restoration of essentially normal gastrointestinal anatomy and function or conversion to an alternate bariatric procedure [28–32]. The long-term outcomes (>8–10 yr) of LAGB, similar to those of other bariatric procedures, remain to be demonstrated [15].

Of the several gastric bands available globally, the 2 most often implanted are the Swedish adjustable gastric band (SAGB, Obtech Medical Sarl, Le Locle, Switzerland and Ethicon Endo-Surgery, Cincinnati, OH) and the Lap-Band (LB; Allergan Medical, Irvine, CA). The SAGB and adjustable gastric banding were introduced in the mid-1980s by Hallberg and Forsell [33] and Kuzmak [34], respectively, and have been consistently reported on in medical publications since then. The LB and SAGB were first implanted laparoscopically in 1993, reported on in 1995 by Belachew et al. [35] and Catona et al. [36] and in 1996 by Forsell and Hellers [37] and Klaiber et al. [38], and are currently the most used and widely studied bands. The SAGB is an investigational device in the United States as of July 7, 2007. The present study sought to assess the efficacy and safety of LAGB as a therapeutic strategy and to compare the SAGB and LB in terms of weight loss, co-morbidity improvement, and complications using a systematic review and meta-analysis of the world data.

Methods

Sources

In July 7, 2003, a prospective protocol was developed to undertake a systematic review [39] of the published medical studies to identify and meta-analytically compare the SAGB and LB outcomes [40]. A broad electronic search was performed using PubMed accessing MEDLINE, Current Contents, and the Cochrane Library, with cutoff dates of January 1, 1998 through April 30, 2006. The following search terms were used: Obesity/surgery [MeSH] OR gastroplasty OR bariatric OR gastric banding, with the delimitation: human, 1998–2006. Manual supplementary reference checks of the accepted studies and reviews within the past 2 years were also performed.

Screening

Two levels of screening were applied (i.e., abstracts for all retrieved studies and full-text review for accepted studies). The acceptance requirements included studies of any design on ≥10 patients who had undergone SAGB or LB implantation and reporting extractable outcomes of interest. The bands must have been placed laparoscopically in ≥85% of patients. The efficacy outcomes (i.e., percentage of excess weight loss, change in BMI, and reduction in absolute weight) were extracted at the 1-, 2-, 3-, and 5-year points, and at the latest point at which ≥50% of the population had follow-up data available. Both early and late safety data (i.e., mortality and band/port/other complications) were required to be extractable by band type. Kin study data (multiple publications using the same study population) were counted only once, as part of the accepted study tabulation. All accepted studies were identified with a Centre for Evidence-Based Medicine (Oxford, UK) level of evidence from I to IV, with I being the best/most complete.

Statistical analysis

The efficacy outcomes of interest were synthesized using meta-analytic pooling of the SAGB and LB results. Meta-analyses of all efficacy outcomes were conducted using a random-effects model. The efficacy outcomes included both raw mean before and after changes (e.g., absolute weight loss) and proportions (e.g., response rates) [41–43]. Bayesian meta-analyses were also conducted for select outcomes to ascertain the robustness of the results. Heterogeneity was assessed using Cochrane's Q statistic. Zeroes were not assumed when not mentioned; rather, the data were treated as missing and were not included in the analyses. Zeroes were imputed for mortality calculations if all patients had been followed up and accounted for.

For studies in which SAGB and LB were studied side-by-side and directly compared, a meta-analysis was conducted for the mean before and after change differences (for continuous outcomes) and odds ratios (for binary outcomes). A positive difference in the before and after changes denoted a greater decrease in a continuous outcome measure in question. An odds ratio of <1 denoted that a given binary outcome occurred more frequently. The meta-analytic mean values and weighted mean differences with

Table 1
Study characteristics

Study characteristic	Total			SAGB			Lap-Band			Direct comparison studies		
	k	t	n	k	t	n	k	t	n	k	t	n
Total	129	147	28,980	33	36	4,273	104	111	24,707	8	17	1,696
Study location												
Europe	83	95	18,416	25	27	3,601	64	68	14,815	6	13	1,304
North America	23	25	5,039	—	—	—	23	25	5,039	—	—	—
Other*	23	27	5,525	8	9	672	17	18	4,853	2	4	392
Study design												
RCT	8	12	478	4	6	209	5	6	269	1	2	180
Nonrandomized comparative study	27	35	3,626	10	11	748	22	24	2,878	5	10	528
Single-arm study	93	99	24,832	19	19	3,316	76	80	21,516	2	5	988
Case control	1	1	44	—	—	—	1	1	44	—	—	—
Prospective	46	55	6,640	14	17	1,447	35	38	5,193	3	7	1,040
Retrospective	83	92	22,340	19	19	2,826	69	73	19,514	5	10	656
Evidence level†												
I	5	8	520	2	3	130	4	5	390	1	2	180
II	16	19	1,108	7	9	489	10	10	619	1	2	156
III	31	36	4,665	7	7	400	27	29	4,265	3	6	320
IV	77	84	22,687	17	17	3,254	63	67	19,433	3	7	1,040
Institutional setting												
Single	114	130	21,801	30	33	3,827	91	97	17,974	7	15	1,516
Multicenter	15	17	7,179	3	3	446	13	14	6,733	1	2	180
Mean follow-up (mo)												
<24	44	51	4,645	12	13	1,002	34	38	3,643	2	5	988
24–35	36	40	6,280	10	11	1,165	29	29	5,115	3	6	365
>36	36	41	14,687	9	10	2,045	29	31	12,642	2	4	291
NR	13	15	3,368	2	2	61	12	13	3,307	1	2	52

SAGB = Swedish adjustable gastric band; k = number of studies; t = number of treatment groups; n = number of patients; RCT = randomized controlled trial; NR = not reported.

* Australia, Egypt, Israel, Saudi Arabia, and Singapore.

† Level of evidence according to Center of Evidence Based Medicine.

95% confidence intervals (CIs), were computed. For calculating the weight loss and co-morbidity outcomes, the latest point at which ≥50% patient follow-up data were available was used. Early (<30 d) and late (≥30 d) complications were summarized by band type and whether the pars flaccida technique was used. Calculations were performed using Statistical Analysis Systems software, version 8.1 (SAS Institute, Cary, NC) and Statistical Package for Social Sciences, version 13.0 (SPSS, Chicago, IL).

Results

Screening outcomes

Of the complete catalogue of SAGB and LB citations identified (n = 4594), level 1 screening rejected 2740 studies. Of the remaining 1854 studies, 1549 were rejected in the level 2 screening. Of the 305 remaining studies, 176 were kin studies for which the data were counted only once in amalgamation with the overlapping data of the 129 "accepted studies" (28,980 patients), all of which were fully extracted and eligible for meta-analysis (see the Appendix of Accepted Studies).

Study characteristics

The accepted studies included 83 European studies (18,416 patients), 22 North American studies (5039 patients), and 24 studies from other locations (Australia, Egypt, Israel, Saudi Arabia, Singapore; Table 1). Most studies were retrospective case series conducted at single centers. Of the studies reporting a median (or mean) follow-up time, 44 reported <2 years of follow-up, 36 studies reported 2–3 years, 36 reported >3 years of follow-up, and 13 did not report on the length of follow-up. SAGB was represented in 36 treatment groups (4273 patients) in 33 studies and LB in 111 treatment groups (24,707 patients) in 104 studies.

Patient characteristics

The baseline demographics were comparable. The mean age, percentage of women, and mean BMI was 39.1 and 40.2 years, 79.2% and 82.5%, and 43.8 and 45.3 kg/m^2 for the SAGB and LB groups). Most patients met the National Institutes of Health [6] criteria for weight loss surgery. The percentages of patients with co-morbidities at baseline were more varied (e.g., 24% of 1083 SAGB patients had hypertension in the 8 treatment arms reporting this characteristic compared with 37% of 3664 LB patients in 28 treatment arms). Too few treatment arms reported on the SAGB baseline co-morbidities to draw meaningful conclusions about patient differences between the groups. In studies providing baseline co-morbidity data, rarely was improvement or resolution reported at follow-up. Also, the follow-up duration varied widely (range 1–98 mo).

A subset of 8 studies (1696 patients) directly compared SAGB and LB [44–51], of which only 1 was a randomized comparison [51]. Of the 6 European studies and 2 from other countries, 3 presented their 3-year results. The SAGB/LB patient baseline demographics were similar to those of the primary accepted studies.

Technique and hospitalization

The vast majority of SAGB and LB patients underwent laparoscopic band placement (87.9% and 98.8%, respectively), with a similar (1.1% and 2.0%) rate of conversion to an open procedure. The pars flaccida technique was used in 16 of 36 SAGB and 28 of 111 LB groups. The investigators often did not explicitly state the technique used, and the accrual years for many cohorts were broad and included both the pars flaccida and the perigastric techniques. The mean length of hospital stay was not significantly different between the groups.

Weight loss

Significant weight reduction ($P < .05$) was observed in the SAGB and LB groups independently when computations using either simple weighted pooling of the estimates of all studies or meta-analytic computations of the mean change were performed (Table 2). At a follow-up of 1, 2, and 3 years, the bands demonstrated steady weight loss, reaching 56.36% (95% CI 48.14–64.58%) and 50.20% (95% CI 43.36–57.0%) excess weight loss in the SAGB and LB groups at 3 years, respectively. In the subset of comparative studies, a meta-analytic comparison at 2 years and at the last point at which ≥50% of patients had follow-up data available showed a statistically significant ($P < .05$) mean difference in absolute weight loss (weighted mean: SAGB, −48.38 versus LB, −41.9; weighted mean difference: −4.84, 95% CI −9.47 to −0.22); at the last point reported, however, the weight loss measures varied widely, from 4 to 36 months.

The change in BMI was consistent and statistically significant ($P < .05$) from the baseline value for both SAGB and LB, independently, at all points (3 yr −11.99, 95% CI −15.20 to −8.77 and −11.81, 95% CI −13.16 to −10.47, respectively). These results were corroborated by a sensitivity analysis of only those SAGB studies with weight loss data at all points (data not shown). An upward bias of the weight loss results because of selective dropout of patients with weight loss failure did not appear to contribute to the findings; the numbers of patients available at each point for the sensitivity analysis were not substantively reduced. Too few studies and heterogeneity of the SAGB and LB percentage of excess weight loss and BMI data precluded meta-analytic comparison of these variables. The weight loss results from the meta-analyses using Bayesian method was not substantively different from the results using a random effects meta-analysis.

Co-morbid disease

For the specific co-morbidities of obesity and their response to LAGB, the number of studies available for either band was somewhat low and the definitions used of changes in categorical outcomes (e.g., resolved, improved, resolved/improved, unchanged, worsened) were often inconsistent, unclear, or not stated. The time frames for improvement were also inconsistently described; only the results for a change from baseline for type 2 diabetes and hypertension included a meaningful number of studies for reporting the meta-analysis (Table 3).

Two SAGB and 14 LB studies reported a statistically significant resolution of diabetes ($P < .05$) in 61.5% of 117 SAGB patients and 60.3% of 249 LB patients at 2 years for those who had diabetes at baseline. Significant reductions in insulin (−67.87 and −70.04 pmol/L, respectively) and fasting blood glucose (−0.89 and −0.63 mmol/L, respectively) provided laboratory substantiation of the clinical outcomes in the SAGB and LB studies. Patients also had high rates of hypertension resolution at 2 years—62.95% of patients in 5 SAGB treatment arms (228 patients) and 43.6% in 12 LB treatment arms (488 patients)—an improvement that persisted for >2 years in 42.9% of SAGB patients. No LB studies reported the results for hypertension after 2 years. The small number of studies precluded a meta-analytic comparison of the changes in co-morbidities.

Complications

Early mortality was equivalent for both devices (.1%), and late mortality was comparable (SAGB .2% versus LB .1%). The incidence of early and late complications was low. Overall, the complication rates for the SAGB and LB appeared similar (Table 4), although a statistical comparison of the complications was not possible owing to the widespread inconsistency in data reporting. For all studies describing complications, the frequency of late slippage or migration (4.0% and 6.2% for SAGB and LB, respectively) and pouch dilation (1.7% and 5.1% for SAGB and LB, respectively) was lower for SAGB. When the analysis controlled for the use of the pars flaccida technique, the differences in the complication rates were reduced (from 4.3% to 2.6% for SAGB and 6.9% to 3.1% for LB). Few other differences in SAGB and LB morbidity were apparent, and all were highly variable in the direction and magnitude of the difference. The number of studies reporting additional

Table 2
Total weight loss outcomes

Outcome	SAGB			Lap-Band		
	t (n)	Weighted mean	Mean change (95% CI)	t (n)	Weighted mean	Mean change (95% CI)
Absolute weight (kg)						
Last follow-up* (yr)	20 (1235)	−46.04	−40.35 (−48.91, −31.79)†	34 (2436)	−33.66	−30.14 (−34.54, −25.74)†
1	10 (877)	−39.22	−41.30 (−50.55, −32.05)†	26 (1541)	−29.12	−28.95 (−31.87, −26.03)†
2	9 (387)	−49.08	−44.98 (−57.18, −32.79)†	15 (803)	−33.21	−34.17 (−39.71, −28.64)†
3	4 (323)	−51.79	−49.89 (−64.18, −35.61)†	7 (501)	−33.93	−37.25 (−50.20, −24.31)†
5	—	—	—	2 (123)	−24.07	—
BMI (kg/m^2)						
Last follow-up*	26 (2459)	−12.25	−12.30 (−14.48, −10.13)†	61 (8217)	−11.05	−10.22 (−11.08, −9.37)†
1	16 (2778)	−9.89	−11.90 (−14.42, −9.38)†	51 (7804)	−10.75	−10.11 (−10.76, −9.46)†
2	13 (2164)	−11.51	−13.69 (−16.94, −10.44)†	37 (4275)	−11.67	−11.32 (−12.10, −10.54)†
3	6 (1560)	−11.10	−11.99 (−15.20, −8.77)†	25 (4495)	−13.00	−11.81 (−13.16, −10.47)†
5	2 (190)	−13.02	—	4 (249)	−11.32	−9.21 (−15.22, −3.20)†
%EWL						
Last follow-up*	12 (2221)	55.28	55.62 (50.04,61.21)†	47 (6251)	43.90	43.57 (39.98,47.15)†
1	9 (1943)	38.83	44.48 (37.35,51.61)†	45 (6204)	42.44	42.97 (40.39,45.56)†
2	6 (1657)	46.49	49.98 (45.86,54.10)†	32 (3540)	50.38	48.14 (43.26,53.01)†
3	6 (1560)	52.63	56.36 (48.14,64.58)†	19 (1659)	54.13	50.20 (43.36,57.04)†
5	2 (190)	56.71	—	6 (823)	51.14	39.76 (27.52,52.00)†

Meta-analysis	Comparative studies only				WMD (95% CI)
	t (n)	Weighted mean	t (n)	Weighted mean	
Absolute weight (kg)	3 (101)	−50.4	3 (147)	−44.07	−4.82 (−9.36, −0.27)‡
Last follow-up*					
1	3 (127)	−41.32	3 (157)	−44.22	2.50 (−1.73, 6.74)
2	3 (101)	−48.38	3 (134)	−41.9	−4.84 (−9.47, −0.22)‡
3	2 (70)	−52.34	2 (112)	−45.96	—
BMI (kg/m^2)					
Last follow-up*	2 (115)	−13.32	2 (123)	−11.1	—
1	2 (130)	−9.76	2 (124)	−10.02	—
2	2 (115)	−12.59	2 (109)	−13.12	—
3	1 (84)	−13.40	1 (88)	−11.6	—
%EWL					
Last follow-up*	2 (672)	51.88	3 (167)	51.24	—
1	2 (677)	45.04	3 (168)	48.24	—
2	1 (84)	55.00	1 (87)	63	—
3	1 (84)	65.00	1 (88)	54	—

SAGB = Swedish adjustable gastric band; t = number of treatment groups; n = number of patients evaluated; CI = confidence interval; BMI = body mass index; %EWL = percentage of excess weight loss; WMD = weighted mean difference (mean difference in pooled groups from comparison studies only).

* Last follow-up available with ≥50% of patients followed up.

† $P < .001$; significant mean effect.

‡ Significant mean effect.

band-related, port-related, or other complications was low, as were the rates of absolute events, rendering the clinical significance of these data uncertain.

In the subset of 8 studies reporting both SAGB and LB results, odds ratios were computed for specific complications, none of which reached statistical significance in favor of either band.

Discussion

This is the first systematic review of the world data (4595 citations) to encompass cumulative studies of the 2 most commonly used LAGBs. The study designs varied and ranged from randomized controlled clinical trials to single-center retrospective reviews.

The most consistently and well-described data among the accepted studies were the weight loss measures. Both bands consistently evidenced statistically significant ($P < .05$) and durable, safe, weight loss (approximately 50% excess weight loss) at 3 years.

The resolution of diabetes and hypertension was significant for both devices and appeared to parallel weight loss at 2 years. As has been shown, the improvement and/or resolution of co-morbidities correlates with even

Table 3
Resolution of co-morbidities

Co-morbidity	SAGB		Lap-Band	
	t (n)	Mean (95% CI)	t (n)	Mean (95% CI)
Diabetes				
Resolved*	2 (117)	61.45 (52.11, 70.78)	14 (249)	60.29 (44.75, 75.83)†‡
Resolved or improved	—	—	13 (436)	83.24 (71.55, 94.93)†‡
Improved	—	—	13 (436)	35.99 (18.92, 53.06)†‡
Unchanged	—	—	9 (245)	16.37 (6.05, 26.69)†‡
Worsened	—	—	2 (54)	22.35 (0.00, 52.10)§
Diabetes measure				
Insulin (pmol/L)	4 (133)	−67.87 (−101.14, −34.60)†	4 (107)	−70.04 (−102.79, −37.28)†‡
HbA1c (%)	—	—	3 (99)	−0.37 (−0.83, 0.09)§
Fasting glucose (mmol/L)	5 (143)	−0.89 (−1.41, −0.37)†	3 (97)	−0.63 (−0.98, −0.29)‡
Hypertension				
Resolved*	5 (228)	62.95 (41.18, 84.72)†	12 (488)	43.58 (30.21, 56.95)†‡
Resolved or improved	1 (235)	74.89 (69.35, 80.44)	11 (942)	70.35 (55.26, 85.43)†‡
Improved	1 (235)	74.89 (69.35, 80.44)	11 (942)	41.36 (33.80, 48.91)†‡

SAGB = Swedish adjustable gastric band; t = number of treatment groups reporting characteristic; n = number of patients evaluated; CI = confidence interval; HbA1c = hemoglobin A1c.

* Discontinued treatment or, for diabetes improvement, reduced treatment.

† $P < .001$ for test of heterogeneity of outcome.

‡ Statistically significant pre- vs. postoperative difference within surgery category.

§ $P < .01$ for test of heterogeneity of outcome.

modest reductions (10–15%) of weight after bariatric surgery [17,52,53].

The common complications recorded for LAGB included gastric prolapse or slippage, pouch dilatation, erosion, and device breakage. The complication profiles for SAGB and LB appeared quite comparable. Very few serious early complications were associated with either band, in contrast to other bariatric operations. Both devices demonstrated minimal long-term complication and failure rates, as evidenced by similar durable weight loss.

In the 129 studies accepted for systematic review, the less well-known co-morbidities were either absent from the population or poorly documented. Future studies should clearly define the characteristics of change in co-morbid diseases measured and the time frames in which the data were recorded. Descriptions of postoperative management were limited, lacked standardization, and primarily comprised only the short or intermediate term. Only a few studies followed up patients for ≥6–10 years and captured information on meaningful numbers of patients at those extended points [21,23,54–56]. Only 8 studies were identified that were designed to directly compare the SAGB and LB performances. Meta-analytic comparisons would be greatly strengthened by the availability of more SAGB studies and more comparative studies of SAGB and LB with intermediate-term (3–10 yr) and truly long-term (≥10 yr, as defined by O'Brien et al. [15]) follow-up for ≥50% of patients.

Both SAGB and LB achieve weight loss and satiety by restriction. The SAGB has been, since its inception, engineered for "low-pressure" restriction, which could have a bearing on the development of long-term complications, and requires additional study. Although not comparable statistically, the meta-analysis findings for both bands were in agreement with the most-cited banding data identifying LAGB, in general, as a safe bariatric procedure. The SAGB was originally designed for implantation using the pars flaccida pathway. This is a technique that has yielded low rates of long-term complications with the SAGB, and, as evidenced in this meta-analysis, has resulted in LB morbidity outcomes also significantly improved compared with those achieved using the perigastric approach [57].

The subset of 8 studies that directly compared SAGB and LB [44–51] included the prospective comparison of short-term SAGB/LB weight loss and complications by Ponson et al. [47], which found no statistically significant differences between these bands, and the prospective, randomized comparison of early SAGB/LB results by Suter et al. [51], which also found no difference in weight loss, food tolerance, or quality of life at 18 months and "identical" rates of late morbidity and reoperation. Each of the SAGB/LB comparative studies independently concluded band comparability.

The statistically significant findings in this meta-analysis for weight loss, resolution of co-morbidities, and mortality with respect to LAGB as a surgical approach to morbid obesity corroborate those of prominent systematic reviews of bariatric outcomes, such as Fielding et al. [12], O'Brien et al. [15], Fried et al. [58], and Chapman et al. [14]. Moreover, the outcomes for banding at 3 years in the present study (laparoscopic implantation for ≥88%; percentage of excess weight loss ≥50%; BMI reduction ≥11.81 kg/m^2; diabetes and hypertension resolution of

Table 4
Complications

Complication	SAGB						Lap-Band					
	Total			Pars flaccida			Total			Pars flaccida		
	t	n/N	%	t	n/N	%	t	n/N	%	t	n/N	%
Mortality												
Early	24	4/3,825	0.1	12	4/1,990	0.2	66	15/14,518	0.1	21	4/5,585	0.1
Late	21	6/3,596	0.2	10	5/1,841	0.3	54	14/10,056	0.1	17	1/3,317	0.0
Band related												
Erosion												
Early	5	0/1,740	0.0	3	0/1,061	0.0	19	4/4,972	0.1	9	3/2,944	0.1
Late	10	23/2,141	1.1	5	20/1,386	1.4	30	140/10,840	1.3	10	42/3,500	1.2
Leakage												
Early	—	—	—	—	—	—	1	4/63	6.3	—	—	—
Late	1	2/625	0.3	—	—	—	5	6/415	1.4	2	1/237	0.4
Slippage/migration												
Early	10	8/2,301	0.3	4	4/1,411	0.3	35	66/8,945	0.7	10	41/2,800	1.5
Late	13	118/2,966	4.0	5	35/1,370	2.6	55	813/13,113	6.2	12	96/3,064	3.1
Port related												
Leakage												
Early	1	0/824	0.0	1	0/824	0.0	8	0/2,868	0.0	2	0/101	0.0
Late	2	19/914	2.1	2	19/914	2.1	16	87/4,331	2.0	5	18/824	2.2
Tubing rupture												
Early	1	0/34	0.0	1	0/34	0.0	9	35/3,954	0.9	6	35/2,404	1.5
Late	4	9/618	1.5	2	2/249	0.8	11	85/4,627	1.8	7	37/2,199	1.7
Dislocation												
Early	4	0/1,004	0.0	4	0/1,004	0.0	14	26/2941	0.9	7	8/1,390	0.6
Late	10	69/2,781	2.5	6	20/1,359	1.5	27	150/4,920	3.0	7	14/935	1.5
Other												
Esophageal dilation												
Early	2	2/230	0.9	2	2/230	0.9	3	0/1,504	0.0	3	0/1,504	0.0
Late	3	11/1,026	1.1	1	2/90	2.2	11	91/5,583	1.6	4	16/1,754	0.9
Pouch dilation												
Early	8	7/863	0.8	4	4/215	1.9	22	51/3,002	1.7	3	0/224	0.0
Late	11	19/1,122	1.7	5	8/430	1.9	32	222/4,372	5.1	6	28/759	3.7
Stomal stenosis												
Early	—	—	—	—	—	—	11	57/3,687	1.5	4	47/2,924	1.6
Late	1	1/26	3.8	—	—	—	8	104/3,143	3.3	1	0/1,014	0.0

SAGB = Swedish adjustable gastric band; t = number of treatment groups; n = number of patients with outcome; N = number of patients evaluated; % = percentage of patients with complication.

≥60.29 and ≥43.58%, respectively; early mortality rate .1%) were clinically meaningful relative to the outcomes benchmarks established in medical studies, such as Buchwald et al. [17,59] and Maggard et al. [60], using the more stringent standard of meta-analysis. Although in this systematic review and meta-analysis of SAGB and LB, only absolute weight loss was appropriate for direct statistical comparison within a small subset of studies, the findings for LAGB as a device class are powerful, demonstrating its safety and statistically and clinically significant efficacy for the short to early-intermediate term.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

Acknowledgment

We would like to acknowledge Jane Buchwald, M.A. and Roy Kulick, M.D. for their substantial contributions to the development of this report.

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